BREAST IMPLANT

This application claims the benefit of U.S. Provisional Application Serial No. 60/061,588, filed October 10, 1997, U.S. Provisional Application Serial No. 60/077,639, filed March 11, 1998, and U.S. Provisional Application Serial No. 60/091,306, filed June 30, 1998, the disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention:

The present invention relates to implantable prostheses. More particularly, the present invention relates to implantable breast prostheses designed to eliminate encapsulation and reduce scarring, and to replace tissue removed for purposes of biopsy or lumpectomy.

2. Description of the Related Art:

Breast prostheses are utilized for augmentation mammoplasty and in cosmetic surgery. Prostheses also are indicated in breast cancer surgery, such as lumpectomies, where a portion of the breast is removed and can leave some disfigurement if not replaced by a similar amount of tissue and/or augmentation material.

Similarly, biopsies can leave small dimples or imperfections if remedial steps are not taken. About 1 million breast biopsies are performed in the United

States annually. As a result, some 200,000 new breast cancers are diagnosed each year.

Known methods of augmentation mammoplasty utilize silicone or saline implants. These have been complicated by encapsulation of the implants, which can occur to varying degrees. Encapsulation produces a hard area of scar tissue around the implant, resulting in a rigid, abnormally-shaped mound beneath the breast tissue or pectoralis muscle, depending upon the placement of the implant.

Moreover, the known implant materials may not be indicated for replacement of smaller amounts of tissue, as would be required to prevent dimpling after biopsies, and they are not amenable to resizing. Further, the known implants are not capable of being implanted through a cannula or needle, and are not readily instilled with medicaments or chemical agents that would be useful in treating the patient.

Accordingly, a need exists for implants and methods that can be adapted for replacement of small as well as large amounts of tissue. A need also exists for implants that can be delivered through cannulae or needles, as well as being able to significantly reduce or eliminate encapsulation, resulting in a prolonged, aesthetically pleasing, soft mound below the breast tissue or pectoralis muscle. In addition, a need exists for implants into which useful substances, such as beneficial medications, chemical agents, hormonal treatments, and radiation media can be instilled to enhance the treatment capabilities of the implant in cancer and other breast pathology.

SUMMARY OF THE INVENTION

The present invention overcomes deficiencies of the prior art, such as those noted above, by providing an implant in which at least the outer portion of the implant, and as much the entire implant, is made of a resorbable material. The implant is sized and shaped to replace excised tissue, supports the surrounding tissue after implantation, and permits the in-growth of fibrous replacement tissue without encapsulation or with reduced scarring.

Accordingly, excised tissue is replaced by implanting an implant having at least an outer shell of resorbable material. The implant is sized and shaped to replace the excised tissue. The implant supports surrounding tissue while fibrous tissue replaces the resorbable portion of the implant.

Advantageously, the implant can be provided in the form of a compressible or non-compressible sponge, or a self-expanding foam. The implant can be instilled with beneficial materials, and can be inserted through a cannula, a needle, or directly inserted.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic elevation of a breast implant according to a preferred embodiment of the present invention.

Fig. 2 is a schematic view of a breast after implantation of the implant of Fig. 1.

Fig. 3 is a schematic view of a breast after implantation of an alternative embodiment of the implant of the present invention.

Fig. 4 is a cross-sectional schematic view of a breast implant according to a second alternative embodiment of the present invention.

Fig. 5 is a schematic view of a breast after implantation of the implant of Fig. 4.

Fig. 6 is a schematic view of a breast implant and a method of insertion according to further alternative embodiments of the present invention, particularly for cases involving the removal of smaller pieces of tissue such as by biopsy and lumpectomy.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to Figs. 1 and 2, an implant **2** has an outer shell **4** made of a biosorbable material woven into a mesh. The inner contents of the implant are fluids such as saline and autologous blood products.

Outer shell **4** is made entirely of a biosorbable material, such as polyglycolic acid, for example, as set forth below. Over a period of approximately three weeks to six months, the outer shell will dissolve, leaving the inner contents **6** present inside the breast. Hard encapsulation will not occur because there is not a foreign body contained within the prosthetic space.

Referring to Fig. 3, implantation of an alternative embodiment of implant **2** is illustrated in

which the outer shell **4** includes both biosorbable material, and non-absorbable material, such as monofilament polypropylene fibers. Outer shell **4** is provided as a mesh or weave of the mixed material, surrounding contents **6** as described above. After a resorption period, contents **6** remain surrounded by a skeletal outer shell made up of non-absorbable fibers **8**, as shown in Fig. 3.

Advantageously, the proportions and spacing of the two types of materials can be altered to provide the desired properties of containment using a minimal amount of nonabsorbable material. Accordingly, the non-absorbable fibers **8** which remain after the biosorbable materials resorb will act as a scaffolding to allow the prosthesis to hold its shape; however, because of the limited amount of foreign material, encapsulation and scarring are decreased.

Referring to Figs. 4 and 5, a second alternative embodiment of the present invention is shown. A prothesis **10** features two capsules, a larger, outer capsule **12** made of biosorbable materials, and a smaller inner capsule **14** made of a non-absorbable material. Inner capsule **14** also can be made partially resorbable as in the first alternative embodiment above. Outer capsule **12** and inner capsule **14** can be separated by a thin layer **16** of saline or autologous fluids such as those described above. Inner capsule **14** surrounds a more permanent prosthesis **18** made of autologous fluids or saline, for example.

After implantation, outer capsule **12** dissolves, thus preventing hardening by encapsulation of the

prosthesis. The supply of fluid **16** between the capsules (a few to several cc.'s) is absorbed by the body once released by the dissolution of outer capsule **12**.

Referring to Fig. 6, a further alternative embodiment of the present invention includes an implant prosthesis **20** provided in the form of a matrix framework, such as a sponge or foam. The implant, which preferably is entirely biodegradable, has a porous structure which supports the surrounding tissue and provides a framework for the in-growth of fibrous tissue material.

According to a preferred embodiment, the implant is provided in the form of a sponge which can be modified by a surgeon prior to implantation, such as at a lumpectomy or biopsy site, simply by trimming the sponge to the appropriate size and shape. Alternatively, the implant can be a pre-shaped prosthesis of appropriate size, or an appropriate amount of foam. Advantageously, the implant can be modified to correspond to the breast tissue that either has been removed, requires replacement, or requires augmentation.

A preferred method of implantation is shown in Fig. 6, whereby the implant is elastically compressible, and is delivered using a cannula or needle **22** inserted into the breast. A single implant **20** is shown being compressed so as to fit within cannula **22**. A force is applied to drive the compressed implant distally through and out the distal end of the cannula into the implant site, where the resilient implant **20** expands to fill the implant site space.

The force for advancing the sponge through the cannula can be applied directly to the implant, or

indirectly using fluids, for example. Advantageously, the implant can be used in conjunction with stereotactic biopsy instrumentation, such as the ABBI System, the MIB System by USS, or the Mammotome System.

As a further alternative, the sponge implant of the present invention can form all or part of a larger implant, such as those described above, to form, for example, all or part of the outer shell **4** of implant **2**. Implantation using open procedures usually would be indicated when the sponge implant of the present invention is used as all or part of a larger implant. Accordingly, the sponge or implant would be placed directly into the biopsy or lumpectomy cavity.

In addition, the implant **20** can be provided in the form of a self-expanding foam, which can be injected by needle or through cannula **22** in a metered amount. Alternatively, a specialized applicator may be used to inject the desired amount of the foam. The amount of foam is preselected to allow sufficient expansion to fill the void left by the excision and support the surrounding tissue to prevent dimpling.

Following insertion of the implant, such as by an open method or one of the stereotactic methods described above, the resorbable implant occupies the breast tissue cavity and supports the surrounding tissue until such time as it is resorbed or biodegrades. After initial implantation, the patient's own fluids and fibroblast permeate the sponge prosthesis. In the case of a small implant, such permeation would occur naturally, subsequent to implantation. In the case of a larger implant, providing the implant at least partially

filled with fluids prior to implantation may be indicated.

Advantageously, the new prosthesis decreases encapsulation after implantation. Various biosorbable materials can be used in the implant of the present invention. Known biosorbable materials include the following:

polyglycolic acid (Dexon, Davis & Geck);
polyglactin material (Vicryl, Ethicon);
poliglecaprone (Monocryl, Ethicon); and
synthetic absorbable lactomer 9-1 (Polysorb, United States Surgical Corporation).

The examples above are designed to last varying lengths of time, after which time they are totally resorbed.

According to the present invention, these products may be mixed with one another or combined to provide various resorption times or gradients, and/or may be interrelated with non-absorbable materials, such as polypropylene or PTFFE (Gortex) material, for example. In an instance where a non-absorbable material is utilized, the non-resorbable implant section will remain partially intact as a permanent structure.

In each of the embodiments, the resorbable portions of the prosthesis ultimately biodegrade, and the patient is left with autologous tissue, some of which may have been implanted, or a permanent implant such as saline, as a filler for the biopsy cavity, thus preserving the contour of the breast and preventing indentation of the overlying skin.

The implants of the present invention further can be instilled, before or after implantation, with

indicated medicines and other chemical or diagnostic agents. Examples of such agents include, but are not limited to, antibiotics, chemotherapies, other cancer therapies, brachytherapeutic material for local radiation effect, x-ray opaque or metallic material for identification of the area, hemostatic material for control of bleeding, growth factor hormones, immune system factors, gene therapies, biochemical indicators or vectors, and other types of therapeutic or diagnostic materials which may enhance the treatment of the patient.

The present invention has been described particularly in connection with a breast implant, but it will be obvious to those of skill in the art that the invention can have application to other parts of the body, such as the face, and generally to other soft tissue or bone. Accordingly, the invention is applicable to replacing missing or damaged soft tissue, structural tissue or bone, or for cosmetic tissue or bone replacement.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.